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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,854	03/21/2002	Andrew Austen Mortlock	Z70601-1	6749

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,854

Applicant(s)

MORTLOCK ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12 and 15-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11, 12 and 15-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment of 8-12-05 has been fully considered. The cancellation of claims 1-10 has overcome the previous rejection of 112/1st paragraph. The amended claims 11, 15 and 16 have overcome the previous rejection of 112/2nd paragraph on all issues except "prodrug", so the previous rejection of 112/2nd paragraph is maintained for "prodrug". However, the amended claim 11 has introduced new matter in the definition of R³⁸. Thus, the following new ground of rejection is necessitated by amendment. Also, applicant's argument has not overcome the previous 103 rejection based on **Thomas et. al.** (US 6,184,225 B1 and 6,291,455 B1).

Therefore, said rejection is maintained herein.

Claims 1-10, 13, and 14 are cancelled.

Claims 17-21 have been added.

Claims 11, 12 and 15-21 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11, 12, 15, 16 and 21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Although the limitation of “ester, amide” has been deleted from claim 11, the limitation of “prodrug” still has indefinite metes and bounds because it is not clear what moiety would constitute a “prodrug”, and where the location of said moiety would be, especially when R¹, R⁴, and R⁷-R⁹ represent substituents that cannot be esterified or amidated.

Claim 21 recites the definition of “prodrug” that includes “alkyl, aryl or aralkyl derivative thereof” which has indefinite metes and bounds because the structure of said derivative is vague and indeterminate.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **New Matter:** Claims 11, 12, and 15-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 has been amended to define R¹⁴ which includes R³⁸. However, the definition of R³⁸ includes substituents that have no support in the specification such as: “nitro,..., oxo, cyanoC₁₋₄alkyl, cyclopropyl, C₁₋₄alkylsulphonylC₁₋₄alkyl,

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C₁₋₄alkoxycarbonyl, di(C₁₋₄alkyl)amino, C₁₋₄alkylaminoC₁₋₄alkyl,..., -C(O)NR³⁹R⁴⁰, -NR⁴¹C(O)R⁴²...”

Claims 12, 15-21 are rejected as being dependent on claim 11 and carrying over the new matter presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11 and 15-19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Thomas et. al.** (US'225). The rejection remains as stated in the previous action and for the following reasons:

a. Applicants asserted that there is no motivation in the reference for one skilled in the art to move the -OH group from the 5th position (*meta*-) to the 4th (*para*-) position on the aniline ring to obtain the claimed compounds. Applicants also pointed out that: “None of the compounds have a hydroxy group at any other position.” Applicants further noted that on column 4, at line 21, R^b, the *para* substituent, does not include -OH (hydroxy) group; however, at line 23, R^c, *meta* substituent, includes the -OH group.

Applicants, then, concluded that: “This [the reference] is clearly providing direction to the skilled person, that where a hydroxy group is present it should be in the meta position.”

b. It is true that in the reference, the hydroxy group is always in the *meta* (or 5th) position. However, the generic formula (I) on column 2 clearly allows any substituents represented by R³ (including hydroxy) to be **anywhere** on the phenyl ring (see column 2, formula I, and the definition of R³ on lines 62-64). While the preferred embodiment has the hydroxy group at *meta* position, it does **not** teach away from the generic disclosure, nor does it negate the motivation found in the generic disclosure.

c. Furthermore, it is within the level of the skilled chemist to make compounds wherein a substituent can be anywhere on the phenyl ring (*ortho*-, *meta*-, or *para*-). For example, the –OH group is known to be *ortho*- or *para*- directing. Thus, to make a *para*-hydroxy-aniline, all one has to do is to react a *phenol* with *N-chloroalkylamine* and a *metallic-ion* catalyst in the presence of sulfuric acid (see reaction 1-6 in Advanced Organic Chemistry by March – cited to show scientific principle). Therefore, the skilled chemist would not have to rely on the hindsight of the instant invention.

d. The motivation for modifying the compound in Example 17 of US'225 comes from the equivalent teaching for substituent R³ at all positions on the phenyl ring as indicated in formula (I) (see column 2). Moreover, it is noted that R³ only represents a handful of moieties, and thus, does not pose a problem for the skilled chemist to select a –OH group in the *para* position.

Thus, at the time that the invention was made, it would have been obvious to make and use compounds as claimed herein in view of Thomas et. al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

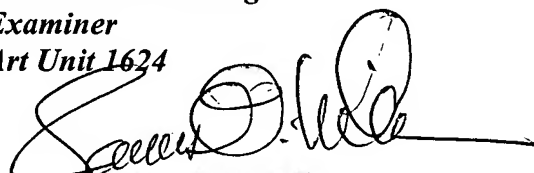


Tamthom N. Truong

Examiner

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10-28-05



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